UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,877	02/22/2002	Ronald A. Schachar	PRES06-00181	9828

7590 11/28/2005

Docket Clerk
P.O. Drawer 800889
Dallas, TX 75380

EXAMINER	
EREZO, DARWIN P	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,877	SCHACHAR ET AL.	
	Examiner	Art Unit	
	Darwin P. Erezo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *22-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 31-61* is/are rejected.

7)☒ Claim(s) *10-21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,522,829 to Michalos.

Regarding Claim 1, Michalos discloses a surgical tool with a blade (22) capable of cutting the sclera of the eye [Fig. 1].

Regarding Claim 6, Michalos discloses a first drive shaft (26) coupled to base housing (12/14). Second drive shaft (20) is coupled (attached) to first drive shaft (26). Third drive shaft (28) is mounted on the drive shaft housing (12/14) at a 90-degree angle with respect to the central axis of the drive shaft housing. Surgical blade (22) is coupled to the third drive shaft (28).

Regarding Claims 7 and 8, Michalos discloses a device having a line, which will inevitably form the junction between section (14) and section (16) of the housing [see Attachment #1]. This line is capable of being used as a reference line during the surgery to guide him in cutting the eyeball.

Regarding Claim 9, Michalos discloses a rotatable support arm (32) with a first end coupled to drive shaft (28) and a second end coupled to blade (22) [Column 6, lines 10-14; Figure 1]. Support arm (32) rotates with the blade. The blade (22) has a curved end [Fig. 1] and another end coupled to support arm (32). The blade is sharp and is capable of being used to cut an incision having the specifications mentioned by Applicant. As noted by Michalos, the depth and size of the incision will correspond to the skill and desire of the surgeon [Column 8, lines 43-52].

3. Claims 1-5 and 31-61 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,328,747 B1 to Nun.

Regarding Claims 1, 31, and 56, Nun discloses a surgical tool for making an incision in the eye and includes a surgical blade (246) [Fig. 18] capable of making an incision having the form of a pocket capable of receiving a prosthesis [Column 15, lines 61-63]. Surgical blade (70) is also capable of such a purpose [Fig. 14; Column 10, lines 42-52]. An incision is considered to be merely a cut or hole in body tissue. Nun discloses putting a prosthesis into the eye [Column 16, lines 6-8].

Regarding Claim 2, blade (70) is curved [Fig. 14; Column 10, lines 46-50] and the user of the device can cut as small or as big incision as the user desires. Particularly, the blade 246 (when it is not spinning) is capable of being used to puncture the sclera and form a very small, linear incision in the sclera.

Regarding Claims 32-34, 42-43, 48-50, 54, 55, and 57-61, Nun discloses a first drive shaft (248), a drive motor (206), and a control cable (not shown) [Fig. 16; Column 17, lines 23-26 and 48-51; Column 12, lines 1-3]. Electric power comes from an

external power source (i.e., electricity) so there would need to be a receptacle to allow the electricity to flow into the motor [Column 17, lines 48-54].

Regarding Claims 4, 35-38, 44, and 45, the surgeon can adjust the speed of the motor using controls [Column 15, lines 36-40]. Furthermore, the surgeon can activate the motor to change the angle of the drill blade relative to an eye tissue prior to cutting, which would be synonymous to positioning the blade for incision.

Regarding Claims 5, 39-41, and 51, Nun discloses a foot switch for controlling the speed of the blade [Column 20, lines 59-62]. Foot switches are capable of receiving control signals from the surgeon, such as depressing the pedal in order to tell the motor to rotate faster.

Regarding Claims 46, 47, 52, and 53, Nun's device is capable of rotating the blade once (in a controlled way) in order to make in incision.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nun in view of US 5,492,528 to Anis.

Nun teaches all the limitations of the claim except for the motor capable of providing a bidirectional motion. However, Nun does teach a drive shaft that can freely rotate (col. 17, lines 23-26). Anis teaches an eye surgical device comprising a blade

17A,17B, a shaft 18, and a motor capable of providing bidirectional motion (col. 4, lines 36-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Nun to use the motor taught by Anis because it would allow the surgeon to reverse the direction of the blade and allow the device/blade to be removed. Moreover, it is well known in the art that most motors are capable of being bidirectional since it merely requires the current to be reversed, as taught by Anis in the recited disclosure above.

Allowable Subject Matter

6. Claims 10-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

7. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

8. Applicant's arguments with respect to claim 3 have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed 9/1/2005 have been fully considered but they are not persuasive.

10. Applicant's arguments regarding the Michalos reference is not persuasive since Michalos teaches each and every structural elements in the rejected claimed invention. The arguments provided by the Applicant is directed towards the functional limitations

recited in the claims. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Again, the functional limitations in the claim merely recite how the device is manipulated, which is irrelevant in a device claim. The applicant is reminded that the claims are not recited as "method claims".

The Applicant also provides the same arguments against the Nun reference. Again, manipulations of the device in the claimed device invention is not enough to overcome the Nun reference since the device taught by Nun is fully capable of being used for any type of surgery. Forming a scleral pocket is merely a functional limitation and can be performed with any type of cutting instrument by a skilled surgeon. It should also be noted that the claimed device invention by the Applicant is not limited for performing eye surgery, i.e., it could be used to cut any type of body tissue. With regards to operating the device to position the blade for incision, the device of Nun is fully capable of being positioned by mere operation of the device. This would be similar to a powered screwdriver with a flat head bit, i.e., operating the screwdriver will rotated the bit and allow for better positioning. Therefore, the surgeon could easily operate the device of Nun to rotate the drill blade for better contact against the target tissue.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

de

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
11/2/05